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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/663,568 | 09/15/2003 | Steven Z. Wu | 50623.335 | 2840 |

7590 09/22/2006

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| EXAMINER | |
|---|---|
| SHEIKH, HUMERA N | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/663,568 | WU ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Humera N. Sheikh
HUMERA N. SHEIKH
Primary Examiner
TC-1600

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/16/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the Application

Receipt of the Preliminary Amendment filed 09/15/03 and the Information Disclosure Statement (IDS) filed 10/16/03 is acknowledged.

Claims 25-33 are pending in this action. Claims 1-24 have been cancelled. Claims 25-33 are rejected.

### *Inventorship*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 25-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang *et al.* (WO 01/01890 A1).**

The instant invention is drawn to a drug-loaded stent, comprising: a radially expanded stent body, a coating layer disposed on the stent body, and polymeric particles containing a therapeutic substance embedded within the coating layer.

**Yang *et al.* (WO '890)** teach stents having polymeric coatings for controllably releasing an active agent, methods for coating a stent and methods for inhibiting restenosis (see Abstract and Claims). The stent has a stent body, a coating disposed over at least a portion of the body, and an active agent releasably dispersed in at least part or portion of the coating. The coating can include a blend of first and second co-polymers (page 3, line 22 – pg. 4, line 6). The stent can be coated by spraying the stent with a solution or dispersion of polymer, active agent and solvent. The solvent can be evaporated, leaving a coating of polymer and active agent. The active agent can be dissolved and/or dispersed in the polymer. In some embodiments, the co-polymers can be extruded over the stent body (pg. 4, lines 12-16).

Yang *et al.* teach at page 7, lines 9-10, that a therapeutic agent can be incorporated into a polymer and applied to the stent as a polymeric surface treatment. Drugs and treatments utilize anti-thrombogenic agents, anti-angiogenesis agents, anti-proliferative agents, growth factors and radiochemicals. Specific examples of therapeutic agents are disclosed on page 7, lines 15-17. In a preferred embodiment, the active agent or therapeutic substance is a restenosis-inhibiting agent (pg. 9, lines 3-4). Processes for surface treatment are disclosed on page 7, lines 18-23. Suitable polymeric materials are disclosed at page 6, line 17 – pg. 7, line 4).

With regard to Applicant's limitations of claims 27 and 33, that recite that the "coating layer is free from any therapeutic substance", the Examiner notes that Yang *et al.* at page 3, lines 22-24, teach that the 'active agent is releasably dispersed in at least part or portion of the coating', thus indicating that the drug is not necessarily entirely released in the coating layer. Hence, this teaching of Yang *et al.* would sufficiently meet the limitations of instant claims 27 and 33.

With regard to the particle size of 0.5 to 2 microns claimed in claim 29., the Examiner points out that suitable or effective particle sizes could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. No unexpected results have been observed, which accrue from the instantly claimed particle size.

It is the position of the Examiner that given the explicit teachings of Yang *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

**Claims 25, 26, 28, 29, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg *et al.* (U.S. Pat. No. 5,464,650).**

The instant invention is drawn to a drug-loaded stent, comprising: a radially expanded stent body, a coating layer disposed on the stent body, and polymeric particles containing a therapeutic substance embedded within the coating layer.

**Berg *et al.* ('650)** teach a drug-containing expandable stent and method for making an intravascular stent by applying to the body of a stent a solution, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent. The inclusion of a polymer in intimate contact with a drug on the stent allows the drug to be retained on the stent during expansion of the stent and also controls the administration of the drug following implantation (see Abstract, Claims and column 2, lines 30-40). The method can be applied by immersing the stent into the solution or by spraying the solution onto the stent (col. 2, lines 40-44). Processes for preparing the coated stent are also disclosed on column 3, line 52 – col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared. The solution is applied to the stent and the solvent is allowed to evaporate, thereby leaving on the stent surface a coating of the polymer and the therapeutic substance. The intravascular stents of Berg *et al.* are directed towards reducing the incidence of restenosis (col. 1, lines 9-67).

Suitable polymers are disclosed at column 4, line 35 – col. 5, line 7. Suitable therapeutic substances are disclosed at column 2, lines 55-62.

With regard to the particle size of 0.5 to 2 microns claimed in claim 29., the Examiner points out that suitable or effective particle sizes could be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. No unexpected results have been observed, which accrue from the instantly claimed particle size.

Thus, it is the position of the Examiner that given the explicit teachings of Berg *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

September 15, 2006

*hns*